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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,087	07/26/2005	Steffen Goletz	08358.0005	7596

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EXAMINER	
SANG, HONG	
ART UNIT	**PAPER NUMBER**
1643	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/522,087	GOLETZ ET AL.	
	Examiner	Art Unit	
	Hong Sang	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 July 2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-13* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

RE: Goletz

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1-3, 7 and 9-11, drawn to a method for the production of a MUC1 molecule which is able to generate an immune response in humans, and a method for identification of a MUC1 molecule which is able to generate an immune response in humans, a method for producing a pharmaceutical composition comprising said MUC1 molecule, wherein the antibody is A76-A/C7.

Group 2, claim(s) 1-3, 7 and 9-11, drawn to a method for the production of a MUC1 molecule which is able to generate an immune response in humans, and a method for identification of a MUC1 molecule which is able to generate an immune response in humans, a method for producing a pharmaceutical composition comprising said MUC1 molecule wherein the antibody is VU-11E2.

Group 3, claim(s) 1-3, 7 and 9-11, drawn to a method for the production of a MUC1 molecule which is able to generate an immune response in humans, and a method for identification of a MUC1 molecule which is able to generate an immune response in humans, a method for producing a pharmaceutical composition comprising said MUC1 molecule, wherein the antibody is VU-11D1.

Group 4, claim(s) 1-3, 7 and 9-11, drawn to a method for the production of a MUC1 molecule which is able to generate an immune response in humans, and a method for identification of a MUC1 molecule which is able to generate an immune response in humans, a method for producing a pharmaceutical composition comprising said MUC1 molecule, wherein the antibody is BC4E549.

Group 5, claim(s) 1-3, 7 and 9-11, drawn to a method for the production of a MUC1 molecule which is able to generate an immune response in humans, and a method for identification of a MUC1 molecule which is able to generate an immune response in humans, a method for producing a pharmaceutical composition comprising said MUC1 molecule, wherein the antibody is VU-12E1.

Group 6, claim(s) 1-3, 7 and 9-11, drawn to a method for the production of a MUC1 molecule which is able to generate an immune response in humans, and a method for identification of a MUC1 molecule which is able to generate an immune response in humans, a method for producing a pharmaceutical composition comprising said MUC1 molecule, wherein the antibody is VU-3D1.

Group 7, claim(s) 1-3, 7 and 9-11, drawn to a method for the production of a MUC1 molecule which is able to generate an immune response in humans, and a method for identification of a MUC1 molecule which is able to generate an immune response in humans, a method for producing a pharmaceutical composition comprising said MUC1 molecule, wherein the antibody is b-12.

Group 8, claim(s) 4-6, 7 and 9-11, drawn to a method for producing cells comprising a MUC1 molecule which is able to generate an immune response in humans, and a method of identifying cells comprising a MUC1 molecule which is able to generate an immune response in humans, a method for producing a pharmaceutical composition comprising said MUC1 cells, wherein the antibody is A76-A/C7.

Group 9, claim(s) 4-6, 7 and 9-11, drawn to a method for producing cells comprising a MUC1 molecule which is able to generate an immune response in humans, and a method of identifying cells comprising a MUC1 molecule which is able to generate an immune response in humans, a method for producing a pharmaceutical composition comprising said MUC1 cells, wherein the antibody is VU-11E2.

Group 10, claim(s) 4-6, 7 and 9-11, drawn to a method for producing cells comprising a MUC1 molecule which is able to generate an immune response in humans, and a method of identifying cells comprising a MUC1 molecule which is able to generate an immune response in humans, a method for producing a pharmaceutical composition comprising said MUC1 cells, wherein the antibody is VU-11D1.

Group 11, claim(s) 4-6, 7 and 9-11, drawn to a method for producing cells comprising a MUC1 molecule which is able to generate an immune response in

humans, and a method of identifying cells comprising a MUC1 molecule which is able to generate an immune response in humans, a method for producing a pharmaceutical composition comprising said MUC1 cells, wherein the antibody is BC4E549.

Group 12, claim(s) 4-6, 7 and 9-11, drawn to a method for producing cells comprising a MUC1 molecule which is able to generate an immune response in humans, and a method of identifying cells comprising a MUC1 molecule which is able to generate an immune response in humans, a method for producing a pharmaceutical composition comprising said MUC1 cells, wherein the antibody is VU-12E1.

Group 13, claim(s) 4-6, 7 and 9-11, drawn to a method for producing cells comprising a MUC1 molecule which is able to generate an immune response in humans, and a method of identifying cells comprising a MUC1 molecule which is able to generate an immune response in humans, a method for producing a pharmaceutical composition comprising said MUC1 cells, wherein the antibody is VU-3D1.

Group 14, claim(s) 4-6, 7 and 9-11, drawn to a method for producing cells comprising a MUC1 molecule which is able to generate an immune response in humans, and a method of identifying cells comprising a MUC1 molecule which is able to generate an immune response in humans, a method for producing a pharmaceutical composition comprising said MUC1 cells, wherein the antibody is b-12.

Groups 15-28, claim(s) 8-12, drawn to a method for producing an antibody, a method for producing a pharmaceutical composition comprising the antibody, the method comprises carrying out the steps of the method according to groups 1-14.
i.e.
Group 15 comprising carrying out the steps of group 1
Group 16 comprising carrying out the steps of group 2
Group 17 comprising carrying out the steps of group 3
.
.
Group 28 comprising carrying out the steps of group 14

Group 29, claim(s) 13, drawn to purified MUC1 molecule which has an immunostimulating effect in humans.

2. The inventions listed as Groups 1-29 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or

corresponding special technical features for the following reasons: the special technical feature linking the Groups I-29 appears to be the purified MUC1 molecule (see claim 13). The purified MUC1 molecule cannot be a special technical feature under PCT Rule 13.2 because it is shown in the prior art. Ryuko et al. (Tumor Bio. 2000, 21:197-210) teach a synthetic 60-mer MUC1 triple tandem repeat peptide with N-acetylgalactosamine (GalNAc) O-linked to the threonine in the PDTR region of each repeat (3M GalNAc). Ryuko et al. teach that monoclonal antibodies were generated against 3M GalNAc (see abstract). Therefore the technical feature linking the inventions is not novel and does not provide contribution over the prior art. As such, unity of invention is lacking and the inventions are deemed to be separate.

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In order for more than one species to be examined, the appropriate additional examination fees must be paid. The species are as follows:

(a) Recovering the MUC1 molecule or the mixture thereof from (see claim 3):

tumor tissues, tumor cells, or the lysate and/or cellular supernatant thereof;

body fluids, or the cell lysate and/or cellular supernatant thereof;

cells, cell lines, or the cell lysate and/or cellular supernatant thereof; and

recombinant cells or cells lines, or the cell lysate and/or cellular supernatant thereof;

(b) Recovering the MUC1 cells, cell lines or sub-cell lines which carry or secrete tumor associated MUC1 molecules or mixtures thereof from (see claim 6):

tumor tissues, tumor cells, or the lysate and/or cellular supernatant thereof;

body fluids, or the cell lysate and/or cellular supernatant thereof;

cells, cell lines, or the cell lysate and/or cellular supernatant thereof;

recombinant cells or cells lines, or the cell lysate and/or cellular supernatant thereof; and

recombinant cells carry and/or secrete immunostimulating molecules.

The claims are deemed to correspond to the species listed above in the following manner: group (a): claim 3

group (b): claim 6

The following claim(s) are generic: 1, 2, 4 and 5.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 for the reasons set forth above.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not

distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

4. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions

unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hong Sang whose telephone number is (571) 272 8145. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Hong Sang, Ph.D.
Art Unit 1643
May 24, 2007

LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER